DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS MAIL

AUG 31 2000

Mr. Bjorn Bergh, Director
Quality Assurance & Regulatory Affairs
Nobel Biocare AB
P. O. Box 5190
SE-402 26 Goteborg
SWEDEN

Dear Mr. Bergh:

During an inspection of your facility located in Goteborg, Sweden on May 22-26, 2000, our investigator determined that your firm manufactures sterile dental implants and dental surgical instruments. These are devices as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act in that Nobel Biocare failed to maintain and implement written Medical Device Reporting (MDR) procedures, as required by Title 21 Code of Federal Regulations (21 CFR Parts 803.17 and 803.50(a)). Additionally, your devices are misbranded for failure to submit information to the FDA, a Report of Correction or Removal, as required by 21 CFR Part 806, promulgated under section 519 of the Act.

21 CFR Part 803

21 CFR 803.17 states that manufacturers will develop, maintain, and implement written MDR procedures to provide for internal systems that provide timely and effective identification, communication, and evaluation of events that may be subject to the MDR requirements and the timely transmission of medical device reports to FDA. Furthermore, 803.50(a) states that device manufacturers are required to report within 30 days whenever they receive or otherwise become aware of information, **from any source**, that a device they manufacture may have caused or contributed to a death or serious injury; or has malfunctioned.

Therefore, even if a complaint received does not originate from the U.S. market, if that same device, or any component or part thereof is sold within the U.S. market, the complaint is subject to the MDR requirements and must be reported. Nobel Biocare violated the MDR regulation by not reporting the complaints for the Contra-Angle Handpiece within the required timeframe.

21 CFR Part 806

21 CFR Part 806.10(b) requires that manufacturers submit a written report to FDA within 10 working days of any correction or removal of a device initiated by such manufacturer if the correction or removal was initiated to reduce a risk to health posed by the device. FDA's classification of Nobel Biocare's recall and the risk analysis performed by [redacted] dated April 7, 2000, are in agreement -- the recall was conducted because of device fractures and the risk posed should the device fracture during surgery, thereby making your recall subject to the 10 working day reporting requirement set forth in Part 806.10(a).

With regard to the Good Manufacturing Practice (GMP) violations identified on the FDA 483 issued at the close of the inspection, it would appear that your response dated June 8, 2000, adequately addresses these 2 items. However, we wish to offer the following for your consideration.

Item #2 on the FDA 483 concerned the failure to conduct input verification bench tests called for in your design control procedures.

Your response indicates that the individual that wrote the report failed to reference historical testing data performed on a similar screw and that the information has since been incorporated into the record to correct this deficiency. This appears to be an acceptable corrective action, although your design control procedure should indicate when it is acceptable to use historical data in lieu of actual testing.

As a preventive action, you indicate that training will be provided for all employees writing design/verification reports. We would also suggest, as a preventive action, that you review your internal audit procedure to determine whether your audit checks are adequate to identify this type of deficiency in the future.

In addition, we wish to receive an explanation as to what actions Nobel Biocare has taken to prevent the type of device failure that occurred with the Contra-Angle Handpieces from happening in the future. In other words, how are you complying with 21 CFR 820.100 Corrective and Preventive Action (CAPA)?

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. As stated above, it appears that the response is adequate for those observations listed. However, with regard to compliance with the MDR, Corrections and Removals, and CAPA requirements, please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations.

Your response should be sent to Sharon Kalokerinos, U.S. Food and Drug Administration, 2094 Gaither Road, Rockville, Maryland 20850.

Sincerely yours,

Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health